Precision of digital implant models compared to conventional implant models for posterior single implant crowns: A within-subject comparison

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Abstract: OBJECTIVE To calculate the precision of the implant analog position in digital models generated from different computer-assisted design and computer-assisted manufacturing (CAD-CAM) systems compared to gypsum models acquired from conventional implant impressions. MATERIALS AND METHODS In five patients in need of a single implant crown, a within-subject comparison was performed applying four different manufacturing processes for the implant model. Each implant was scanned with three different intraoral scanners: iTero Cadent (ITE), Lava True Definition (LTD), and Trios 3Shape (TRI). All digital implant models were fabricated using the corresponding certified CAD-CAM workflow. In addition, a conventional impression was taken (CON) and a gypsum model fabricated. Three consecutive impressions were acquired with each impression system. Following fabrication, all implant models were scanned. The datasets were aligned by a repeated best-fit algorithm and the precision for the implant analog and the adjacent teeth was measured. The precision served as a measure for reproducibility. RESULTS Mean precision values of the implant analog in the digital models were 57.2 ± 32.6 µm (ITE), 88.6 ± 46.0 µm (TRI), and 176.7 ± 120.4 µm (LTD). Group CON (32.7 ± 11.6 µm) demonstrated a statistically significantly lower mean precision value for the implant position in the implant model as compared to all other groups representing a high reproducibility. The mean precision values for the reference ranged between 31.4 ± 3.5 µm (TRI) and 39.5 ± 16.5 µm (ITE). No statistical significant difference was calculated between the four treatment groups. CONCLUSIONS The conventional implant model represented the greatest reproducibility of the implant position. Digital implant models demonstrated less precision compared to the conventional workflow.

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Abstract

Objective: To calculate the precision of the implant analog position in digital models generated from different CAD-CAM systems compared to gypsum models acquired from conventional implant impressions.

Materials and methods: In five patients in need of a single implant crown a within-subject comparison was performed applying 4 different manufacturing processes for the implant model. Each implant was scanned with three different intraoral scanners: iTero Cadent (ITE), Lava True Definition (LTD), and Trios 3Shape (TRI). All digital implant models were fabricated using the corresponding certified CAD-CAM workflow. In addition, a conventional impression was taken (CON) and a gypsum model fabricated. Three consecutive impressions were acquired with each impression system. Following fabrication, all implant models were scanned. The datasets were aligned by a repeated best fit algorithm and the precision for the implant analog and the adjacent teeth was measured. The precision served as a measure for reproducibility.

Results: Mean precision values of the implant analog in the digital models were 57.2±32.6 µm (ITE), 88.6±46.0 µm (TRI), and 176.7±120.4 µm (LTD). Group CON (32.7±11.6 µm) demonstrated a statistically significantly lower mean precision value for the implant position in the implant model as compared to all other groups representing a high reproducibility. The mean precision values for the reference ranged between 31.4±3.5 µm (TRI) and 39.5±16.5 µm (ITE). No statistical significant difference was calculated between the four treatment groups.

Conclusions: The conventional implant model represented the greatest reproducibility of the implant position. Digital implant models demonstrated less precision compared to the conventional workflow.

Introduction

The conventional fabrication of implant restorations is based on a traditional gypsum cast poured from a physical impression with an elastomeric impression material. The accurate transfer of the implant position and angulation to the physical model is a prerequisite for achieving a precisely fitting implant restoration.

The quality and precision of the conventional impression technique may be influenced by a number of parameters, including e.g. the impression material, the angulation of the implant, existing undercuts of neighboring structures, and the type of impression copings and techniques (Sorrentino, Gherlone, Calesini, Zarone, 2010) (Lee, So, Hochstedler, Ercoli, 2008). In addition, the laboratory process for the fabrication of the implant model involves several sensitive steps (e.g. dimensional stability of the materials) (Christensen, 2008a) (Christensen, 2008b).

Alternatively, implant impressions can be taken by means of digital technology (Beuer, Schweiger, Edelhoff, 2008). A scan body is mounted onto the implant serving as a digital reference structure. The implant position is then captured using an intraoral scanner (IOS). Subsequently, the implant analog model is fabricated by means of a computer assisted design and computer assisted manufacturing (CAD-CAM) technique (Guth, Keul, Stimmelmayr, Beuer, Edelhoff, 2013). Depending on the location of the CAD-CAM system, different workflow protocols are available (chair side, laboratory, or centralized production) (Kapos, Evans, 2014). In implant dentistry, however, often a centralized fabrication for the digital implant model is involved (Patel, 2014).

From a clinical point of view, an accurate transfer of the implant position to the model is a prerequisite. Accuracy is described by trueness and precision. Trueness describes the deviation of the impression geometry from the original geometry and precision describes the degree of reproducibility between repeated impressions rather than to the original geometry

(Ender, Mehl, 2014). Trueness and precision can be calculated for in-vitro studies, whereas clinical studies are limited to the evaluation of precision.

Various in vitro and clinical studies were performed in the past to analyze trueness and precision comparing IOS versus the conventional impression technique (Ender, Attin, Mehl, 2015a) (Ender, Zimmermann, Attin, Mehl, 2015b). An in-vitro study demonstrated, that IOS showed similar accuracy compared to the highly accurate conventional technique for full-arch impressions(Ender, Mehl, 2015). In clinical studies, unilateral IOS achieved a level of precision similar to conventional impression techniques (Ender, et al., 2015a), whereas for full-arch impressions the precision with the conventional impression technique was greater (Ender, et al., 2015b). In general, these studies demonstrated that various digital workflows rendered a sufficient accuracy of the impression as compared to a conventional workflow.

To date, no clinical scientific evidence is available reporting on the precision for the transfer of the clinical implant position to a physical model with an implant analog comparing digital workflows and a traditional impression technique.

The aim of the present clinical study was, therefore, to calculate the precision of the implant analogs in digital models generated from different CAD-CAM systems and of gypsum models acquired from conventional implant impressions. The null hypothesis was that the precision of the implant analog in digital models of different CAD/CAM systems and conventionally fabricated models is similar.

Materials and Methods

This study was designed as a controlled clinical trial applying a within-subject comparison of 4 different manufacturing processes for implant analog models. The study was conducted at the Clinic of Fixed and Removable Prosthodontics and Dental Material Science, Center of Dental Medicine, University of Zurich, Zurich, Switzerland. The trial was approved by the local ethical committee (2016-00876-2, Kantonale Ethik-Kommission, Zurich, Switzerland).

Study population

Five patients in need of a single implant crown were included. The subjects had to fulfil the following inclusion criteria:

- ≥ 18 years of age
- Full-mouth plaque scores (FMPS) and full-mouth bleeding scores (FMBS) < 25%
- No active periodontal disease
- Presence of a single tooth implant (Straumann RN implant, Basel, Switzerland) in need of a crown in regions 14-17, 24-27, 34-37, 44-47 (FDI)
- healthy or sufficiently restored adjacent and antagonist teeth

A signed informed consent was obtained from all the patients prior to the start of the investigation.

Clinical and laboratory procedures

One clinician (S.M.) performed all clinical procedures. The clinician was experienced with the tested digital impression systems, and has an expertise for the different CAD/CAM systems.
In all implant sites, the emergence profile had been conditioned prior to the final impression by means of a provisional implant reconstruction. Following the removal of the provisional crown,

a sealed envelope containing the randomization sequence of the impression procedures was opened.

For each optical impression, a new scan body (Straumann Scan Body, RN) was hand tightened onto the implant (Straumann Scan Body, RN). Three digital systems for intraoral optical impression and inter-maxillar registration were tested:

- iTero Cadent (group ITE; Align Technology Inc., San Jose CA, USA)
- Lava True Definition (group LTD; 3M ESPE, Seefeld, Germany)
- Trios (group TRI; 3Shape Copenhagen, Denmark).

Prior to scanning with group LTD, a titanium dioxide powder was applied to the tooth and scan body surface (Lava Powder for Chairside Oral Scanner; 3M ESPE). Quadrant scans were performed and the scan sequences were chosen according to the manufacturers' guidelines.

In group CON, a plastic stock impression post (Straumann Impression cap and cylinder, RN) was fixed onto the implant and the correct position was checked manually. A metal stock impression tray (ASA Permalock; ASA Dental, Bossano, Italy) was used and a tray adhesive (3M Polyether Adhesive, Neuss, Germany) applied to the impression tray. Closed-tray impressions were made using an elastomeric material (Permadyne Polyether Impression Material, Neuss, Germany).

Three consecutive impressions were acquired for each implant and each impression technique, resulting in a total of 15 implant analog models per manufacturing process. All impressions were controlled for accurate imprint of the impression post, of the interproximal and occlusal surfaces of the adjacent teeth.

Subsequently, the following implant analog model were fabricated:

- Group ITE: The scan data was sent by a certified connection to the inbox of the CAD/CAM software (Cares Inbox, Visual 10, Straumann). The implant model was designed by means of CAD (Cares Visual 10, Straumann) and milled in a centralized

production facility (Straumann, Leipzig, Germany).

- Group LTD: The scan data was sent by a certified connection to the inbox of the CAD/CAM software (Cares Inbox, Visual 10, Straumann). The implant model was designed by means of CAD (Cares Visual 10, Straumann) and printed in a centralized production facility (Print@Dreve, Dreve Dentamid GmbH, Unna, Germany).
- Group TRI: The scan data was sent by a certified connection to the inbox of the CAD software (3Shape dental system, Copenhagen, Denmark). The implant model was designed by means of CAD (3shape dental system, dental designer 2017) resulting in a stereolithography (STL) data format. The STL file of the implant model was nested by means of a CAM software (3Shape Model Builder, Version 2017). Thereafter, the implant model was printed using a laboratory-based printer (Objekt Eden 260V, Stratasys, Rehovot, Israel).
- Group CON: The metal implant analog (RN synOcta analog, Straumann) was fixed onto the impression caps. After minimal 24 hours of dry storage, the impressions were poured with scannable Type IV dental stone (quadro rock plus, Picodent, Wipperfürth, Germany). The impression tray was removed from the stone cast after 40 minutes. Subsequently, the stone model was stored at ambient temperature and humidity for at least 96 hours until the expansion of stone was complete.

Outcome variables

Precision of the implant analog models:

Each implant model was optically scanned using a high resolution scanner at 6 µm precision (D103i, Imetric 3D SA, Courgenay, Switzerland). Prior to scanning, a scan body (Straumann Scan Body, RN) was screwed on the implant analog. Digital implant models were matted with scan powder to reduce scan errors (Stimmelmayr, Guth, Erdelt, Edelhoff, Beuer, 2012). The

scan data was exported in an STL data format. The mean precision was measured for the scan body (area of interest) and the adjacent teeth (reference). Initially, the scan data from each patient were superimposed with an 'automatic alignment' command through the inspection software (Geomagic Verify v4.1.0.0;3D Systems Inc). In each scan data irregular parts of the gum, including the vestibule, and areas beyond 2 mm from the marginal gingiva were cut out to ensure a more accurate fine registration. Trimmed data were registered again by a 'best-fit align' command to match the point cloud composing each data (Fig. 1a). All regions except the scan body (area of interest) were cut out and the file was saved separately keeping the three-dimensional coordinate system (Fig. 1b). Accordingly, the adjacent teeth were processed in order to determine the quality of the alignments (Fig. 1c). For the measurement of precision, the trimmed scan data acquired from 3 scans by each scanner system were paired, and these 3 pairs were inspected (scan 1 versus scan 2, scan 1 versus scan 3, scan 2 versus scan 3). Deviations between polygons formed by the point cloud constituting the 2 superimposed scans were calculated and the distance data of all superimposed pairs were summarized.

Statistical analysis

A power analysis was carried out. The data originated form a clinical study assessing the precision for unilateral dental impressions (Ender, et al., 2015b). A sample size of 15 in each group will have 80% power to detect a difference in means of 11 µm to a conventional impression with a mean of 18.8 µm, assuming the common standard deviation is 10.5 µm.

Data was coded in Excel and all statistical analyses were done with the statistical software R (R Foundation for Statistical Computing) including the package PMCMR (T, 2014) for pairwise posthoc comparisons. Continuous variables were reported by using mean, standard deviation (SD) and interquartile range (IQR). Differences between treatment groups were calculated using Kruskal-Wallis test followed by Conover's test. Resulting P values were corrected with the Holm adjustment for multiple testing. Differences within treatment groups

between scan body (area of interest) and adjacent teeth (reference) were calculated using Wilcoxon signed rank test. The level of significance was set at $\alpha = 0.05$.

Results

The five patients had a mean age of 51.4 years (range: 24 to 68 years). The study implants were 3 molar sites in the maxilla and 2 molar sites in the mandible. In four implant sites, neighboring adjacent teeth (mesial and distal) were present, whereas in one implant site, a neighboring adjacent tooth was present at the mesial aspect only. In total, for each of the 5 patients, three models were fabricated for each of the 4 workflows. This resulted in a total of 12 models per patient and 15 models per manufacturing process.

Mean precision values of all groups are shown in Table 1 and Figure 2. Mean precision values of the scan body in the CAD-CAM implant models were 57.2 ± 32.6 µm (ITE; highest precision), 88.6 ± 46.0 µm (TRI), and 176.7 ± 120.4 µm (LTD; least precision). The differences between the three digital manufacturing processes were statistically significant (ITE vs. TRI $p=0.018$; ITE vs. LTD $p < 0{,}001$; LTD vs. TRI $p=0.027$). The mean precision of group CON was 32.7 ± 11.6 µm. The differences between group CON and all three digital manufacturing processes were statistically significant (vs. TRI $p < 0{,}001$; vs. ITE $p=0.018$; vs. LTD $p < 0{,}001$).

The mean precision values for the superimposition of the adjacent teeth ranged between 31.4 ± 3.5 µm (TRI) and 39.5 ± 16.5 µm (ITE) (Table 1). No statistically significant differences were calculated between the four treatment groups ($p>0.05$).

The difference between the precision values of the adjacent teeth to the scan body was statistically significant in group TRI ($p < 0{,}001$) and LTD ($p < 0{,}001$). No statistically significant differences were calculated within groups TRI and CON ($p>0.05$).

Discussion

The present within-subject comparison of four manufacturing processes for implant analog models demonstrated that mean precision values i) were significantly more favourable for the conventional compared to all digital workflows; ii) varied significantly between the three digital workflows; iii) were similar for the superimposition of adjacent teeth in all groups. Therefore, the null hypothesis was rejected.

In a conventional workflow, the accurate transfer of the implant position to the implant model is a prerequisite for a well-fitting implant restoration. In contrast, in a digital workflow using an intraoral scanner, the implant crown is designed on a virtual implant model. Subsequently, the implant model and the reconstruction are fabricated independently using CAD/CAM technologies. In the dental laboratory, the digital implant model then serves as a reference for the dental technician to finalize the implant crown before delivery. This final step usually includes veneering and/or staining for aesthetic purposes and a verification of interdental and occlusal contacts.

The present study revealed that up to the fabrication of the models, all workflows resulted in a high precision without significant differences between the groups. This was demonstrated by a verification through the superimposition of references structures (neighboring teeth) and using a highly accurate reference scanner. The present results confirm an earlier clinical study assessing the precision of unilateral impressions in different workflows (Ender, et al., 2015b). It was demonstrated that the mean precision of digital unilateral impressions methods for the IOS ranged between 21.8 µm (LTD) and 49.0 µm (ITE) and achieved a level of precision similar to the precision values of this study ranging from 31.4 µm (TRI) and 39.5 µm (ITE).

The present study showed, however, that the conventional workflow rendered a superior precision in terms of the implant analog position compared to all three digital manufacturing processes. The precision for the implant analog in the conventional cast was 24.5 µm, whereas the precision in the digital implant models ranged between 57.2 µm and 176.7 µm. This is in

agreement with in vitro studies (Lee, Betensky, Gianneschi, Gallucci, 2015) (Basaki, Alkumru, De Souza, Finer, 2017). The vertical position of the implant analog in a milled implant model was reported to be significantly more coronal than the reference implant in the master model (Lee, et al., 2015). In a clinical scenario with 2 posterior implants on each side of the mandible, digital casts were less accurate than those fabricated with the conventional impression technique (Basaki, et al., 2017).

The outcomes of the present study are supported by in vitro experiments. In vitro models might therefore serve as reliable screening methods rendering similar outcomes to clinical studies. Still, the present study revealed the importance of clinical data. This was predominantly demonstrated by the fact that the digitally fabricated implant analog models had a substantially lower precision and reproducibility. Several parameters might explain these outcomes including: i) the manual placement of the scan body onto the implant as well as of the implant analog in the digital model, ii) the type of manufacturing process (additive vs. subtractive), iii) the quality of the CAM devices, iiii) the type of materials used for the models.

Manual steps appear to be a critical element for the digital workflow in implant dentistry. An in vitro study demonstrated that the fit of the scan bodies on the lab analogs was better than on the original implants (Stimmelmayr, et al., 2012). Therefore, an imprecise positioning of the scan bodies could explain the lower reproducibility in the digital implant analog models in the present study. In addition, digital implant models are designed and manufactured containing a housing for a metallic prefabricated implant analog. The implant analog is manually placed into its housing and has a passive fit. Therefore, the implant analog position in a digital model depends on an accurate reproduction of the geometry of the housing and a correct manual positioning. In contrast, in the conventional implant model the implant analog is permanently fixed by the surrounding dental stone cast.

The type of manufacturing process for the three digital implant models was different. The digital model can be fabricated by means of subtractive or additive processes (Lebon,

Tapie, Duret, Attal, 2016a; Lebon, Tapie, Duret, Attal, 2016b) (Revilla-Leon, Gonzalez-Martin, Perez Lopez, Sanchez-Rubio, Ozcan, 2017). Differences regarding the reproduction of the surface quality of digital models were described previously. An in-vitro study demonstrated that milled digital models showed less anatomical details as compared to conventional gypsum models (Lee, et al., 2015). Still, the present study showed that the highest precision for the implant analog position was achieved, when a digital workflow with a subtractive technology was applied.

In the present study, the fabrication of the digital implant models was based on three different so-called certified workflows. Still, the fabrication of the implant model may either be laboratory based or involve a centralized production facility. One might speculate that a centralized fabrication with industrial processes results in a more standardized and superior quality of the implant models. However, the present study showed that a laboratory based additive manufacturing process (group TRI) rendered a higher reproducibility for the implant analog as compared to a centralized workflow (group LTD). The present study confirms the results of an in vitro study that the accuracy of implant analog positions on casts depends on the technology used (Revilla-Leon, et al., 2017).

The outcomes are limited to some extent by the fact that a clinical study can only report on precision. There is no reference available and the deviation of the model geometry to the original geometry cannot be calculated (Ender, Mehl, 2014). Therefore, no information is available on the type of deviation (e.g. angulation and vertical position of the implant analog). The precision, however, describes the deviation between repeated impressions and serves as a measure for reproducibility.

The results of the present study indicate that the implant analog model does not serve as a reliable reference for potential modifications and verifications of the reconstructions prior to the delivery to the patient. Since the fabrication of the model and the crown are independent, one might speculate that the reconstruction would still fit intraorally. Three clinical studies with

a total of 66 monolithic implant crowns generated from a model-free digital workflow could be delivered successfully without any clinical adjustments (Joda, Bragger, 2014; Joda, Bragger, 2016)(Joda, Ferrari, Bragger, 2017). These results, however, are only valid for the specific CAD-CAM system and implant system. In addition, a clinically/technically acceptable precision of implant analog models is unknown. It may be speculated that the precision of the implant analog position in group ITE is sufficient as no statistically significant difference was calculated within the group. Still, the precision might even differ between the various workflows, but be individually optimized for the intraoral scanner, the CAD software and the CAM device.

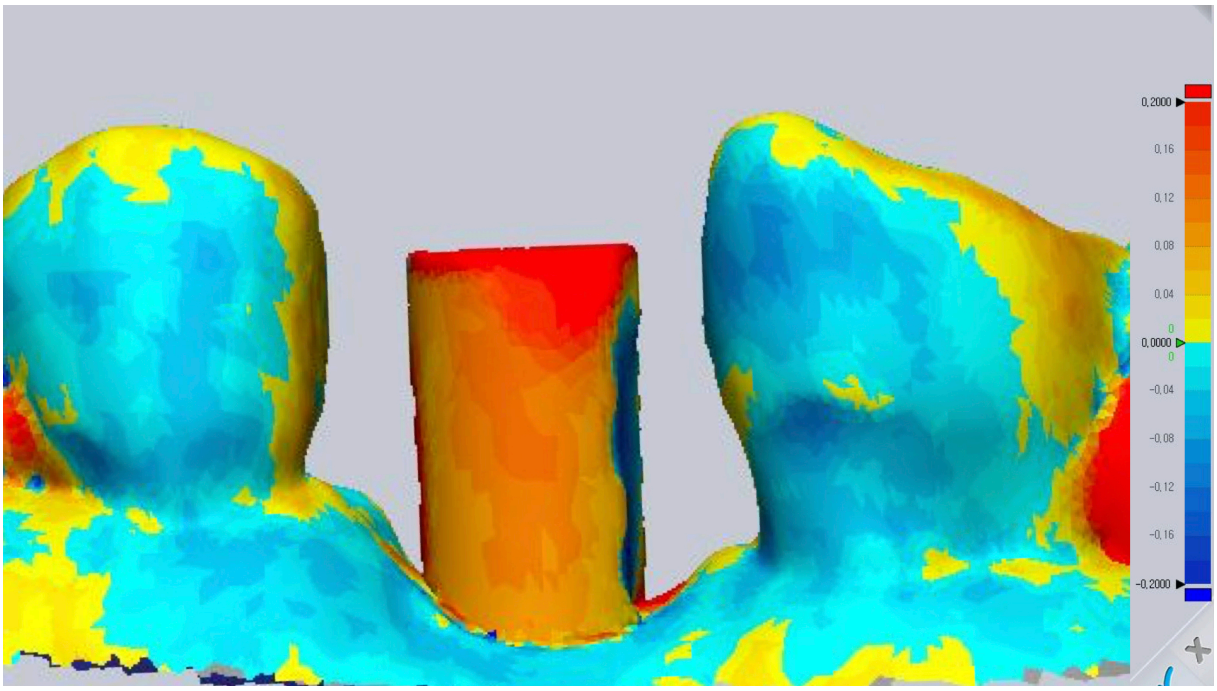
Conclusions:

Mean precision values for the fabrication of implant analog models were significantly more favourable for the conventional compared to all digital workflows. Currently, digital implant models cannot serve as reliable reference for the dental technician independently of the CAD-CAM system used. Adjustments for reconstructions should therefore not be made on these digital models or a model-free fabrication should be considered.

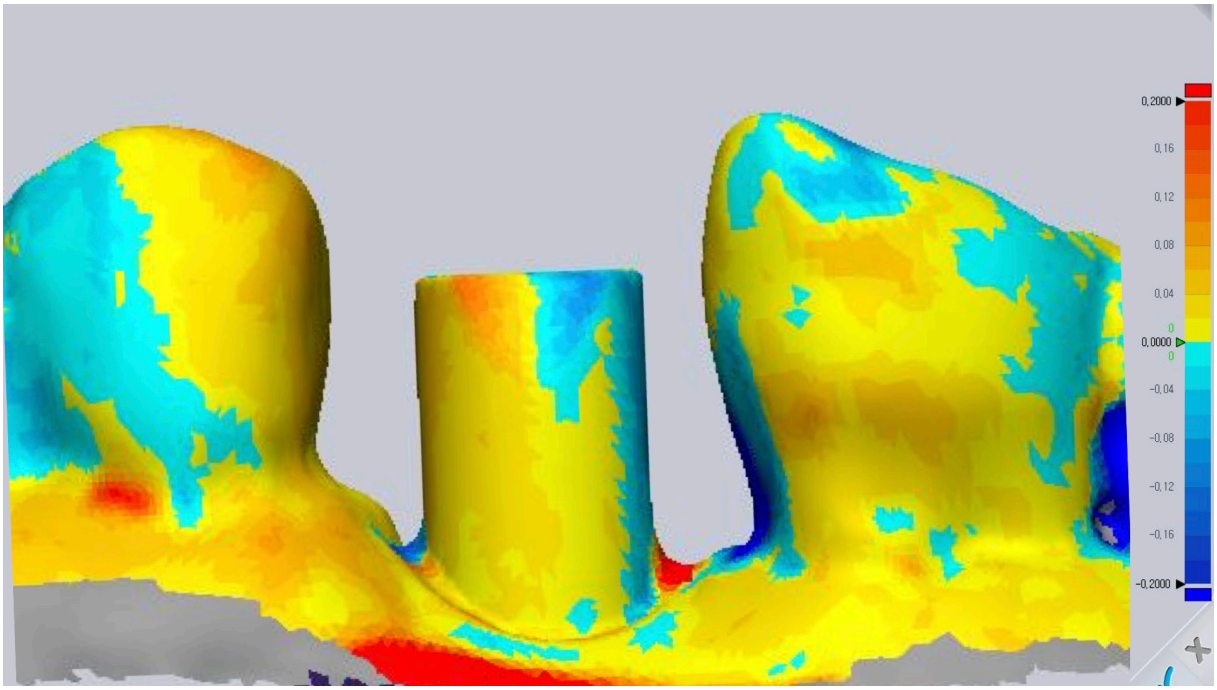
Figure legends

Fig 1 Differences between two STL files from the same impression modality after a best fit alignment by a 3D inspection software (a) group TRI, (b) group ITE (c), group LTD, and (d) group CON. Color-coded scale represents the discrepancy of matching (yellow/light blue = 0.0 µm, orange/medium blue=+/-500 µm, red/dark blue=1000µm).

a)



b)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-0,16
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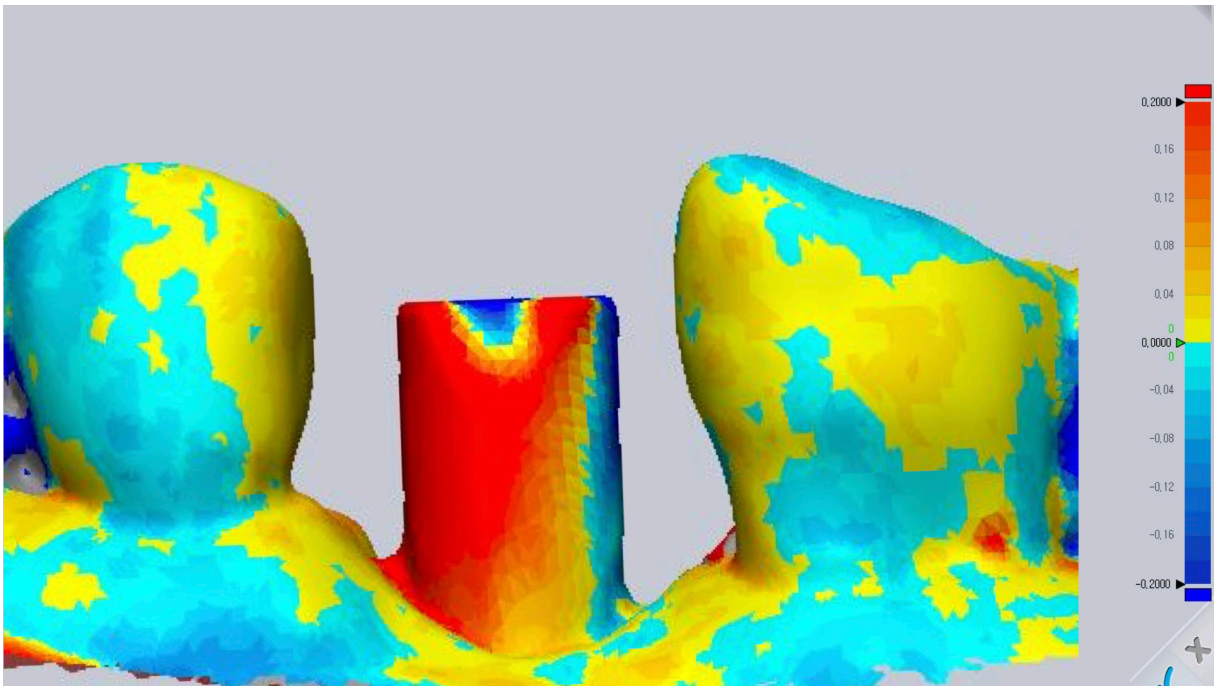
c)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d)

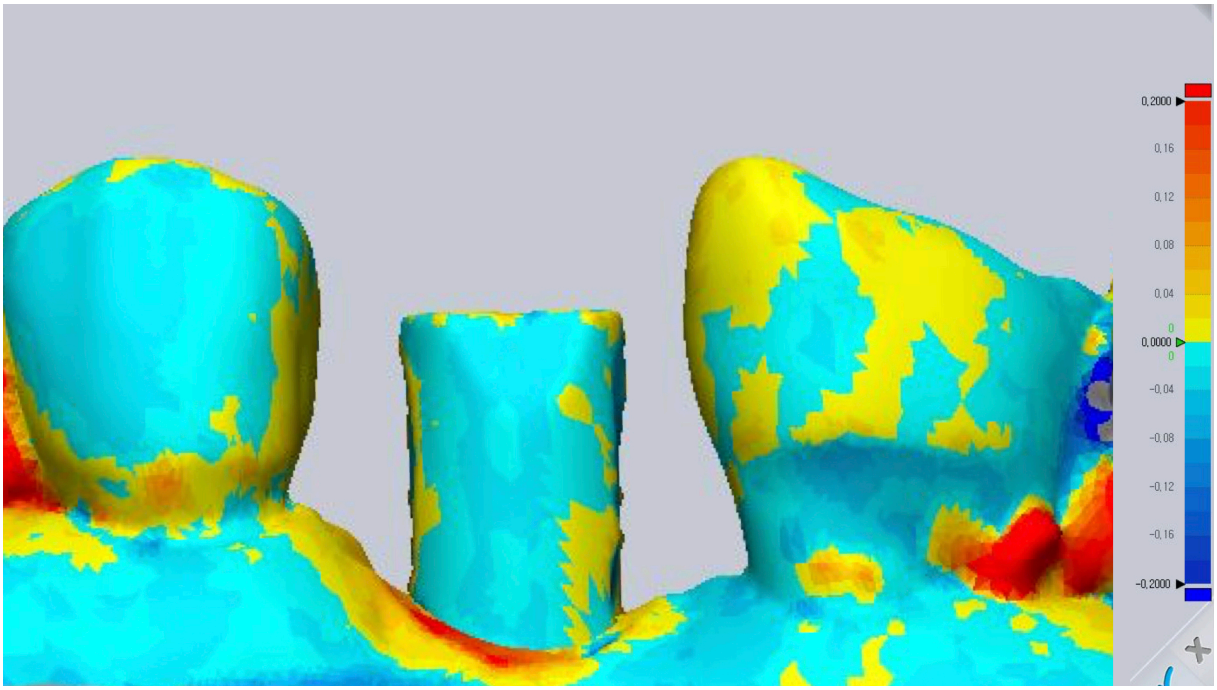
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Fig 2 Boxplot for precision values (μm) of the conventional gypsum model (CON) and the digital implant models (TRI, ITE, LTD)

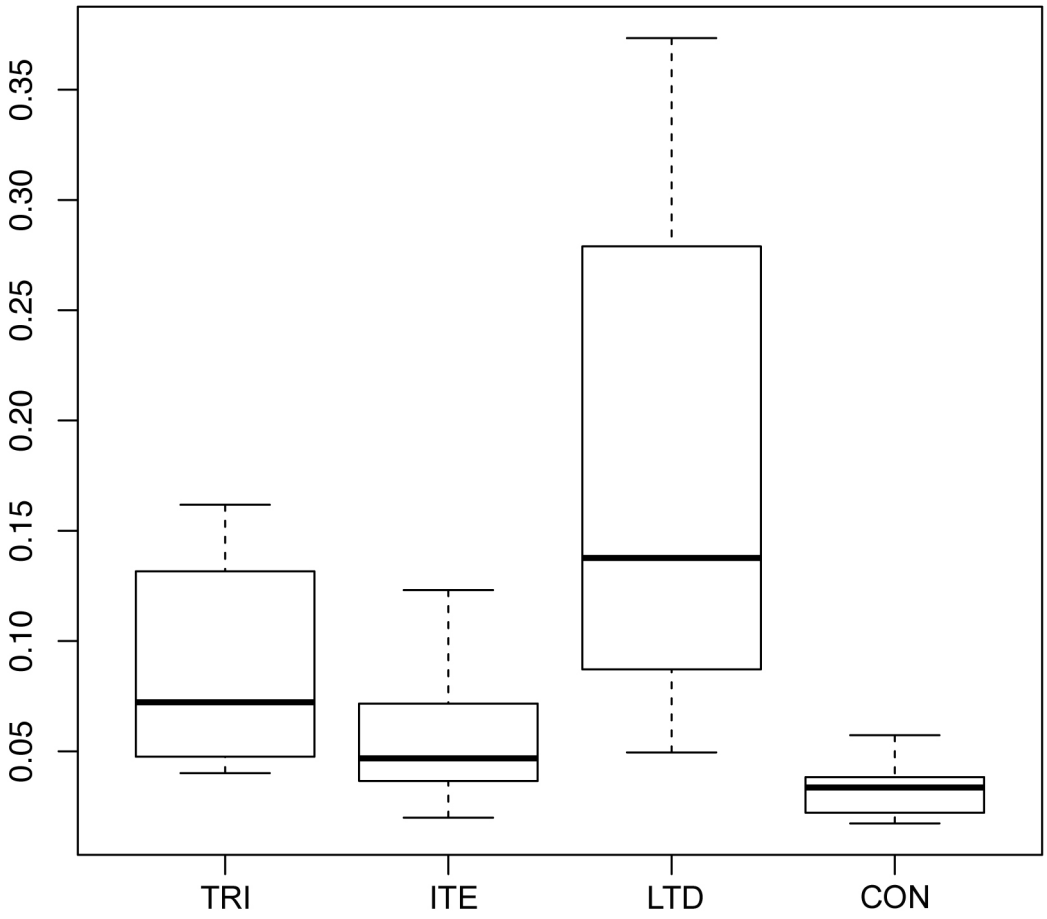

Table 1 Mean precision values (µm) including standard deviation (SD) and interquartile range (IQR) for the scan body and the adjacent teeth in the conventional gypsum model (CON) and the digital implant models (TRI, ITE, LTD).

	scan body			adjacent teeth		
	mean	SD	IQR	mean	SD	IQR
TRI	88.6	46.0	84.0	31.4	3.5	3.8
ITE	57.2	32.6	35.1	39.5	16.5	17.8
LTD	176.7	120.4	191.8	31.6	6.7	9.2
CON	32.7	11.6	16.2	33.4	17.2	22.9

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